

## REMARKS

**Office action summary.** Claims 1-28 and 38-59 are provisionally rejected for obviousness-type double patenting over claims 1-3, 7-16, and 21-61 of copending application No. 10/359,548 (which is the parent application). All pending claims 1-59 are rejected as not enabled.

These rejections are traversed for the reasons indicated below.

**Amendment to the specification.** The specification is amended as provided by the CREATE Act to note a joint research agreement.

**Claim amendments.** Claim 1 has been amended to include a variation of the solubility limitation formerly found in claim 15. The new limitation in claim 1 is additionally supported, for example, by the specification at paragraph [00114]. Claim 9 has been amended to require that the backing member be comprised of acrylate polymers from the chosen list, thus excluding from its scope compositions where the backing member is not comprised of an acrylate polymer. Claim 15 has been amended to eliminate a limitation similar to that inserted into claim 1. Claim 50 has been amended to make it an independent claim rather than a dependent claim. There is no intent to change its scope.

**Obviousness-type double patenting.** The provisional obviousness-type double patenting rejection is not well taken because the Examiner is ignoring the limitation, present in all claims, requiring that “the backing member is comprised of a polymer composition that erodes in a moist environment at a slower rate than the hydrogel.”

The Examiner writes that “With respect to the backing member, absent a clear showing of criticality, the determination of a backing member material is within the skill of the ordinary worker as part of the process of normal optimization.” (Office Action at 4.) The test for obviousness is not, however, whether a person of skill in the art might be able to find a backing member meeting the erosion limitation, once that person has been informed of the limitation. Instead it is whether *the limitation itself* is obvious over the *claims* (not the disclosure) of the parent ’548 application.

The Examiner does not point to anything in the ’548 claims which suggests an erodible backing member at all. The Examiner reasons that “the hydrogel tooth whitening formula would not be bound to a user’s teeth if the backing member would erode prior to the hydrogel

formulation.” (Office Action at 5.) However, this is not necessarily so – the composition containing the whitening agent could itself have some degree of adhesion to the teeth. A backing member which is itself erodible is not the only possible option for tooth whitening. Such a backing member in any event not been shown to exist in the prior art, so one must ask oneself why, if such a backing member was obvious, it did not show up before the present invention.

In sum, there is thus no sufficient basis for finding that the backing member erosion limitation is obvious over the cited claims of the '548 application.

**Enablement rejection.** The Examiner has rejected all claims as not enabled.

Enablement need only bear a reasonable relationship to the scope of the claim. *See, e.g., Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005) (“The scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.”) (quoting *In re Fisher*, 427 F.2d 833 (CCPA 1970)). There is no need for everything within the scope of the claim to be enabled. For example, there is no requirement to enable future inventions that fall within the scope of the claims. *CFMT, Inc. v. YieldUp International Corp.*, 349 F.3d 1333 (Fed. Cir. 2003).

“Enablement is not precluded by the necessity for some experimentation such as routine screening.” *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

It is useful to consider here the problem faced by a person of skill in the art who has been given the requirement to design a backing member that will erode more slowly than the hydrogel that contains the active, and has the benefit of the teaching of the current application. The hydrogel can be assumed known at the time, its composition already decided upon, and thus its erosion rate can be readily measured or assessed qualitatively. All that is needed to practice the invention at that point is to find *some polymer* having slower erosion and otherwise suitable for use in the backing member (e.g., biocompatible, adequately stable, not having unwanted interaction with the active).

The specification lists a number of classes of suitable polymers (pp. 29-31). Many of them come in grades, as the Eudragits do. Many of them can be plasticized, potentially affecting erodibility. The specification specifically discusses Eudragits. The specification describes some ways, such as solubility control, by which a suitable Eudragit-containing composition that erodes more slowly than a given hydrogel can be obtained. Eudragit backing members will, for many

applications, be sufficient to practice the invention. They can be used not only where the hydrogel also contains acrylic polymers, but also more broadly. “[T]he enablement requirement is met if the description enables any mode of making and using the invention.” *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998).

Even if for some reason, the person of skill in the art elected not to use a Eudragit polymer for the backing member, and chose instead to use a different class of polymer as recited in certain dependent claims, it would in general take only routine experimentation to find a suitable polymer within the class. The experimentation is routine because it is seeking to achieve a desired value for a single variable – the speed of erosion. The experimentation is not seeking to optimize that variable or to achieve extreme values of that variable in an inhospitable environment, but reasonable values in a moist environment – the erosion time of the hydrogel would not be expected to be extreme (at least in a drug delivery application). The experimenter is also not seeking a specific value for the variable, but rather a composition with a rate of erosion that falls somewhere within the broad range that is slower than the (known) rate of erosion for the hydrogel containing the active. Furthermore, one of ordinary skill in the art would be aware of a variety of ways in which the speed of erosion can be affected - either positively or negatively. Notably, erodibility is correlated with water solubility, as explained in the application itself. A solubility limitation has been added now to claim 1 in recognition of this correlation. It is likely that water solubility will already be known in a commercially available polymer. Erodibility can be affected through blending and additives as explained in the application at paragraph [00114]. The experimenter can also affect erodibility through such parameters as the density of the backing member and the choice of crystallinity, molecular weight, and degree of crosslinking of the polymer or polymers of which it is made. In addition, as the Examiner has noted (Office Action at 10), the level of skill in this art tends to be quite high. For all of these reasons, no more than routine experimentation would be needed to practice the invention.

The Examiner has rejected as non-enabled not just claim 1 but also dependent claims such as claim 15. Claim 15 requires that both the backing member and the water-swella-

water-insoluble polymer<sup>1</sup> comprise acrylate polymers. The Eudragits are believed to be widely used and representative types of acrylate polymers. The Examiner has noted in the Office Action (p. 8) the existence of a discussion in the specification relating to the situation where Eudragits are used in both the backing member and the water-swellaable, water-insoluble polymer. The Examiner has not pointed to any inadequacies in that discussion. Thus, the Examiner has not pointed to any reason why claim 15 would not be enabled.

**Conclusion.** For the reasons indicated above, it is requested that the rejections of record be withdrawn and all pending claims allowed. If the Examiner has any questions or concerns, it would be very much appreciated if he would telephone the applicants' counsel at (650) 251-7700.

Respectfully submitted.

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August 17, 2006

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<sup>1</sup> Please note that "water-insoluble" is expressly defined at paragraph [0045] of the specification and allows for a modest degree of water solubility.